Health Advisory:

Cases of *Fusarium* keratitis in Multiple States

April 21, 2006

This document will be updated as new information becomes available. The current version can always be viewed at http://www.dhss.mo.gov

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Office of the Director
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Telephone: (800) 392-0272
Fax: (573) 751-6041
Web site: http://www.dhss.mo.gov

Health Advisory
April 21, 2006

FROM: **JULIA M. ECKSTEIN**
DIRECTOR

SUBJECT: **Cases of *Fusarium* keratitis in Multiple States**

The Centers for Disease Control and Prevention (CDC) is currently investigating cases of *Fusarium* keratitis occurring in persons from multiple states including Missouri. As of April 9, 2006, a total of 109 patients with suspected *Fusarium* keratitis were under investigation. The investigation, although incomplete at this time, has detected an association of some cases with a Bausch & Lomb ReNu® brand contact lens solution or a generic-brand solution manufactured by Bausch & Lomb. CDC, state and local health departments, and the Food and Drug Administration (FDA) are presently seeking to determine whether this cluster of cases represents an increase of *Fusarium* keratitis infections and to determine the association, if any, of these cases with any product.[1]

On April 13, Bausch & Lomb, according to a press release,[2] "asked U.S. retailers to remove ReNu® with MoistureLoc® from their shelves temporarily, and recommended that consumers switch to another lens care solution for the time being, until the investigation of reports of fungal keratitis infections among contact lens wearers in the United States is concluded."

On April 14, 2006, FDA issued the following statement[3] regarding the voluntary withdrawal of Bausch & Lomb ReNu MoistureLoc® Contact Lens Solution from the market.

> FDA is continuing to work closely with the Centers for Disease Control and Prevention (CDC) and Bausch & Lomb to investigate the source of *Fusarium* keratitis eye infections. The agency supports Bausch & Lomb's decision to voluntarily withdraw ReNu MoistureLoc® contact lens solution from the market until the agencies have had a chance to conclude their investigation.
>
> FDA started its investigation of the Bausch & Lomb manufacturing plant on March 22, 2006, and will continue inspections of the Greenville, SC manufacturing plant and other facilities through next week. While the investigation continues, FDA will work with CDC to identify and confirm cases of *Fusarium* keratitis reported by state health departments and from FDA Medwatch reports.
>
> FDA and CDC are advising consumers to take precautions to reduce their risk for *Fusarium* keratitis through preventive practices for contact lens wearers that include:
>
> - Wash hands with soap and water, and dry (lint-free method) before handling lenses.
> - Wear and replace lenses according to the schedule prescribed by the doctor.
> - Follow the specific lens cleaning and storage guidelines from the doctor and the solution manufacturer.
> - Keep the contact lens case clean and replace every 3-6 months.
> - Remove the lenses and consult your doctor immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling.
>
> For more information, please visit FDA's Contact Lens and Eye Infections page at: http://www.fda.gov/oc/opacom/hottopics/contacts.html.

Microbial keratitis is a severe infection of the cornea. Risk factors for infection include trauma (generally with plant material), chronic ocular surface diseases, immunodeficiencies, and rarely, contact lens use. The annual incidence of microbial keratitis is estimated to be 4-21 per 10,000 soft contact lens users, depending on whether users wear lenses overnight. Fungal keratitis is a condition more prevalent in warm climates; in the southernmost United States, up to 35% of microbial keratitis cases are fungal keratitis, compared with 1% in New York. The proportion of fungal keratitis attributable to *Fusarium* spp. also varies by region, from 25% to 62%. First-line treatment includes topical and oral antifungal medications; patients who do not respond to medical treatment usually require surgical intervention, including corneal transplantation. *Fusarium* keratitis is not transmitted from person to person.[1]

Clinicians evaluating contact lens users with signs or symptoms of keratitis, such as unusual redness, eye pain, tearing, discharge, or sensitivity to light, should consider fungal keratitis and refer the patient to an ophthalmologist, if appropriate. Clinicians should consider obtaining clinical specimens (e.g., corneal scrapings) for culture before initiating treatment.[1] Clinicians or microbiology laboratories should report cases of *Fusarium* keratitis to their local public health agency, or to the Missouri Department of Health and Senior Services (DHSS) at 866-628-9891, or 800/392-0272 (24/7).

Fusarium isolates should be submitted to CDC. Health care providers should contact the Microbiology Unit at the Missouri State Public Health Laboratory (MSPHL) at 573-751-0633 to receive a specimen submission number **before** shipping the specimen to CDC. Shipping information is contained in the Appendix (see pages 3-5, below). Shipping information can also be obtained at http://www.dhss.mo.gov/Lab and clicking on the *Fusarium* Keratitis Specimen Submission Instruction link.

References

1. CDC. *Fusarium* keratitis --- multiple states, 2006. *MMWR* 2006;55(Dispatch):1-2. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d410a1.htm

2. Bausch & Lomb. *News Release: Bausch & Lomb Asks Retailers to Remove U.S.-Manufactured ReNu® with MoistureLoc® from Shelves; and Recommends Consumers Switch to Another Solution Pending Investigation of Reports of Fusarium Infections Among Contact Lens Wearers.* April 13, 2006. http://www.bausch.com/4_13_pressrelease.pdf

3. FDA. *FDA Statement Regarding Voluntary Market Withdrawal of Bausch & Lomb ReNu MoistureLoc® Contact Lens Solution*. April 14, 2006. http://www.fda.gov/bbs/topics/NEWS/2006/NEW01357.html

Appendix
Fusarium Keratitis Investigation: Specimen Handling Document

Isolates

All fungal isolates suspected to be *Fusarium* species should be processed in the following manner:

- Subculture fungal isolate in pure growth to an appropriate nutritional medium.
- Incubated at 25 degrees.
- Observe daily for visible growth of slant.
- Ship after visible growth has occurred.
- Complete Isolate Specimen Submission Report and e-mail to Lynette Benjamin at CDC (Lbenjamin@cdc.gov).
- Ship isolates in dry, ambient condition and in accordance with CDC guidelines. (See Packing Diagnostic Specimens for Transport, below.)
- Ship isolates to:

Attn: Fusarium Keratitis Investigation
DASH
Centers for Disease Control
1600 Clifton Road
Atlanta, Georgia 30333

CDC Contact: Lynette Benjamin 404/639-5475

Environmental specimens

All environmental samples to be submitted for testing in association with *Fusarium* keratitis investigation should be processed in the following manner:

- Ship in dry, ambient condition.
- Ensure that all fluids are secure from leakage.
- Complete Environmental Specimen Submission Report and e-mail to Judith Noble-Wang (JNobleWang@cdc.gov) AND Lynette Benjamin (Lbenjamin@cdc.gov).
- Ship environmental specimens to:

Attn: Fusarium Keratitis Investigation
Centers for Disease Control
DASH
1600 Clifton Road
Atlanta, Georgia 30333

CDC Contact: Judith Noble-Wang 404/639-2321

Packing Diagnostic Specimens for Transport

A diagnostic specimen is any human or animal material being transported for research, diagnosis, investigational activities, disease treatment or prevention BUT excluding live infected animals. Those known or suspected of containing Category A pathogens must be shipped as infectious substances (UN 2814 or UN 2900) unless otherwise indicated on the Category A List.

Primary packaging

- Primary container must be water tight. Seal screw top containers with adhesive tape, parafilm, or something similar.
- Wrap multiple containers individually to prevent breakage.
- Δ Primary containers cannot contain more than 1 L (liquids) or 4 kg (solids). **Everything in the primary container, including transport media, is considered the diagnostic specimen.**

Secondary packaging

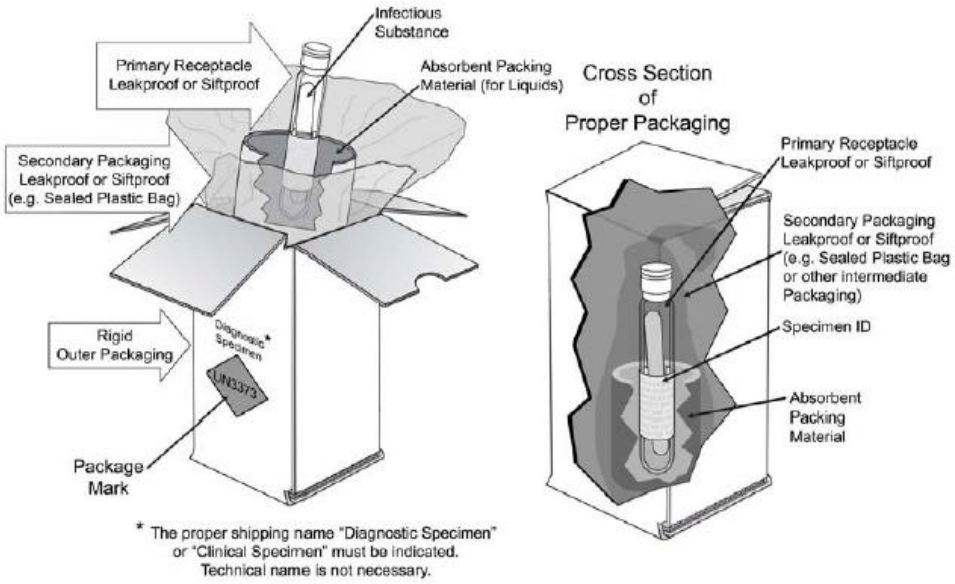
- Use enough absorbent material to absorb the entire contents of all primary containers in case of leakage or damage.
- Secondary packaging must meet the IATA packaging requirements for diagnostic specimens including 1.2 meter (3.9 feet) drop test procedure.
- Δ Secondary packaging must be watertight (liquids) or siftproof (solids). Follow the packaging manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging must be at least 100 mm (4 inches) in the smallest overall external dimension.
- Must be large enough for all markings, labels, and shipping documents (e.g., air waybill).

Outer packaging

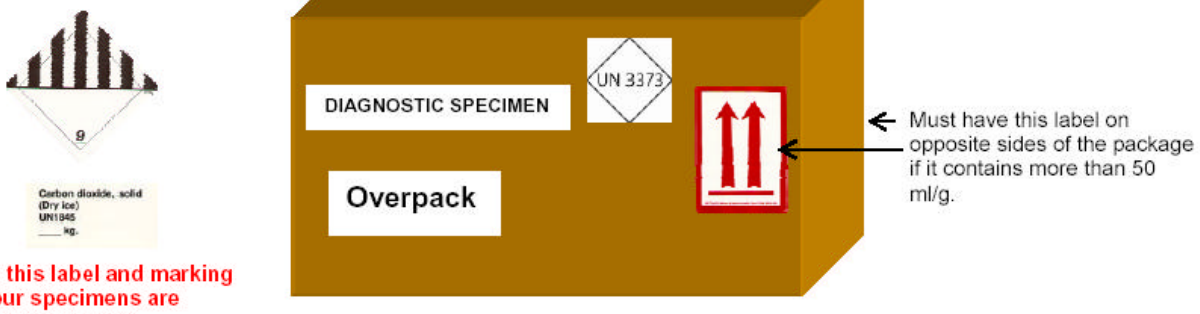
- An overpack is used if the secondary packaging is not large enough for all the labels, markings, and documents OR if cold packs or dry ice is used.
- The outer packaging must not contain more than 4 L or 4 kg.
- Both dry ice and wet ice must be placed outside the secondary packaging.
- Dry ice: packaging must permit the release of carbon dioxide gas and not allow a build-up of pressure that could rupture the packaging.
- Wet ice: the packaging must be leak-proof.
- Each package and the air waybill must be marked with the following text (exact wording):

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. Place in a sealed plastic bag to protect from moisture.
- If overpack used, package must be marked "Overpack." All secondary package markings must be on the overpack.
- The name, address, and telephone number of the responsible person must be on the package and the air waybill.
- You must put the words "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS" and "UN 3373" in the "Nature and Quantity of Goods" box on the air waybill.
- A Shipper's Declaration for Dangerous Goods is **NOT** required.

Packing and labeling of diagnostic specimens



Example of outer packaging (overpack) for diagnostic specimens



Add this label and marking if your specimens are packed in dry ice.